



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/171,928 10/05/98 INOMATA

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EXAMINER

BORIN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

08/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Advisory Action**

Application No.

09/171,928

Applicant(s)

Inomata et al.

Examiner

Michael Borin

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED \_\_\_\_\_ FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Jul 2, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: SEE ATTACHED

4. ☐ Applicant's reply has overcome the following rejection(s):  
\_\_\_\_\_  
\_\_\_\_\_
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
SEE ATTACHED  
\_\_\_\_\_  
\_\_\_\_\_
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 6, 8-14, and 21
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other:

MICHAEL BORIN  
PRIMARY EXAMINER  
ART UNIT 1631

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### DETAILED ACTION

Amendment and response after final is acknowledged.

The amendment is not entered because it will necessitate new grounds of rejections. At least, a rejection under 35 U.S.C. 112, second paragraph, will be required as some of dependent claims are drawn to non-intravenous forms of administration, while the independent claim is now limited to continuous administration. As applicant directs to pages of the specification describing continuous intravenous administration as proof of written description for a continuous administration (see response, page 4, lines 9-10), the term "continuous administration" is read as meaning intravenous administration.

Applicant's comments regarding difference of the claimed method is noted. Examiner maintains that the referenced methods comprise the same method step, even though the particular mechanism as instantly claimed is not addressed in the reference. It is not possible to discern which particular mechanism was engaged in achieving an overall effect of treatment. Even though separate mechanisms might have been demonstrated in specifically designed model conditions, Examiner assumes that the referenced method inherently included the effect as instantly claimed.

As for comparison of dosages in the instant and referenced methods, first, it will require additional consideration. Second, unlike a particular example in the specification, the claims are not limited to a particular dosage range. Third, a cursory look at dosage recalculations presented, shows that dosage in Blaine administered to humans (0.03  $\mu\text{g/kg/min}$ ) is not significantly different from

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dosage in the instant method (0.025  $\mu\text{g/kg/min}$ , which is the dosage recalculated from rat into human dose using very rigid parameters).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael Borin  
Primary Examiner  
AU1631

